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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,356	07/22/2002	Michele Trucks	VET-1	9079
23599	7590	09/17/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			SWARTZ, RODNEY P	
		ART UNIT		PAPER NUMBER
		1645		

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/088,356	TRUCKSIS, MICHELE
	Examiner	Art Unit
	Rodney P. Swartz, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 28June2004.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 2-10,21,22,25,41-47,50 and 77-89 is/are pending in the application.

4a) Of the above claim(s) 2-5,41,42,46,50 and 77-83 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 6-10,21,22,25,43-45,47 and 84-89 is/are rejected.

7) Claim(s) 6 is/are objected to.

8) Claim(s) 2-10,21,22,25,41-47,50 and 77-89 are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

1. Applicant's Supplemental Response to Office Action, received 28June2004, is acknowledged. Claims 1, 19 have been canceled. Claims 6 and 47 have been amended.
2. Claims 2-10, 21, 22, 25, 41-47, 50, and 77-89 are pending. Claims 2-5, 41, 42, 46, 50, and 77-83 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to a nonelected invention.
3. Claims 6-10, 21, 22, 25, 43-45, 47, and 84-89 are under consideration.

### **Rejections/Objections Moot/Withdrawn**

4. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis, is moot in light of the cancellation of the claim.
5. The rejection of claim 19 under 35 U.S.C. 112, first paragraph, written description, is moot in light of the cancellation of the claim.
6. The rejection of claims 6-8, 45, and 47 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claims.

### **Rejections/Objections Maintained**

7. The objection to Figure 11 for lacking sequence identifiers is maintained for reasons put forth in the original objection.
8. The rejection of claims 43-45 and 47 under 35 U.S.C. 112, first paragraph, enablement, is maintained for reasons put forth in the original rejection.

Applicant argue that the specification provides numerous examples of *M. tuberculosis* virulence genes selected in accordance with the claimed methods utilizing *M. marinum*.

The examiner has considered applicant's argument, but does not find it persuasive. While the specification may teach that genes of *M. marinum* and *M. tuberculosis*, the

specification does not teach nor provide sufficient guidance for the scope of the claimed invention, i.e., a pharmaceutical composition of avirulent *M. tuberculosis* or an attenuated *M. tuberculosis* vaccine.

9. The rejection of claims 6-10, 19, 21, 22, 25, 43-44, 47, and 84-89 under 35 U.S.C. 112, first paragraph, written description, is maintained for reasons put forth in the original rejection.

Applicant argues that the specification provides numerous examples of *M. tuberculosis* virulence genes selected in accordance with the claimed methods utilizing *M. marinum*.

The examiner has considered applicant's argument, but does not find it persuasive. While *M. marinum* and *M. tuberculosis* may have similar properties, the specification does not provide sufficient guidance/information to conclude that similar nucleic acid sequences in *M. tuberculosis* are actually virulence genes.

#### **New Objections/Rejections Necessitated by Amendment**

10. Claim 6 is objected to because of the following informality: step g begins "dentifying" which should be "identifying". Appropriate correction is required.

#### **Conclusion**

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire

on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

September 15, 2004